UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,305	01/14/2005	Toru Ishibashi	1232-5579	9351

27123 7590 09/13/2007
MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	**PAPER NUMBER**
1634	

NOTIFICATION DATE	DELIVERY MODE
09/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com
Shopkins@Morganfinnegan.com
Tquinones@Morganfinnegan.com

Office Action Summary	Application No.	Applicant(s)	
	10/521,305	ISHIBASHI ET AL.	
	Examiner	Art Unit	
	Narayan K. Bhat	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is written in reply to applicant's correspondence filed July 19, 2007. Claims 1-24 are pending in this application. Claims 1-13 are withdrawn. New claim 24 was added. Applicant's arguments filed on July 19, 2007, have been fully considered but they are not persuasive for reasons addressed in this office action. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

2. Claims 14-24 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14-17 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et al (USPN 5,688,642 issued November 18, 1997).

Regarding claim 14, Chrisey et al teaches a method of immobilizing a probe to a solid phase carrier that include providing a DNA oligomer having thiol group, i.e., mercapto group (Fig. 3, See top panel- DNA oligomer with –SH group, Chrissey et al also refers to DNA oligomers as nucleic acid molecules, i.e., NAMs) and further teaches that DNA oligomers have a C3-C6 spacer molecules, i.e., linker molecule (column 9,

lines 54-61) thus teaching a probe having a linker containing –SH group. The –SH group of Chrissey et al is the first functional group of the instant claim.

Chrissey et al further teaches an amino silane coating of the silica substrate (Fig. 4, element # 42, column 6, lines 45-47), thus teaching an immobilization substrate having an aminofunctional group. The amino functional group of Chrissey et al is the second functional group of the instant claim.

Chrissey et al also teaches that the substrate (column 6, lines 46-47) having an aminosilane coating thereon (Fig. 4, element # 42) binds electrostatically with negatively charged DNA oligomer (Fig. 4, DNA oligomer-element # 48; left bottom panel, column 6, lines 45-54) and further teaches that DNA oligomer immobilized via electrostatic means on an organosilane monolayer is able to form duplexes selectively with its complementary partner, but will reject hybridization with a mismatched oligomer (Column 12, lines 57-61), thus teaching imparting the probe to the immobilization substrate and by inherency, teaching binding of first functional group of the probe and the second functional group of the immobilization substrate to each other.

The mercapto and the amino group taught by Chrisey et al are also the acidic and basic functional group as defined in the instant specification (see instant specification, Paragraph 0036). Teachings of electrostatic binding, i.e., ionic interactions of DNA oligomer having the first functional group and immobilization substrate having second functional group of Chrisey et al thus encompass also first functional group and second functional group in the state of coupling without covalent binding.

Regarding claims 15 and 23, Chrisey et al teaches first functional group, that is mercapto group and the second functional group that is the amino group. These inherently are acidic and basic groups as defined in the instant specification (see instant specification, Paragraph 0036). The dissociation constant of amino group is 1.0×10^{-6} (See the instant specification, Paragraph 0025) and the mercapto group is 1.0×10^{-12} or more and the dissociation constants are inherent properties of the functional groups that are chosen and both the groups of the instant claim are taught by Chrisey et al. Furthermore when the thiol group or the amino group binds to each other, causes a change in the properties that are inherent to the " thiol and amino groups" including the mutual chemical shift of signals in the NMR spectrum.

Regarding claims 16 and 17, Chrisey et al teaches that probe comprises of a DNA oligomer (Fig. 1, element # 19) and the spacer, i.e., linker is between the DNA and the thiol group (Column 9, lines 54-61) which is at the 3' terminal (Fig. 3, top panel; see the –thiol group at the 3' end of the DNA oligomer), thus linker is at the 3' end.

Regarding claims 19 and 20, as described previously, Chrisey et al teaches the thiol group, that is mercapto group as the first functional group and the primary amino group (-NH2 group) as the second functional group (Fig. 3) and are the acidic and basic functional groups.

Regarding claim 21, Chrisey et al teaches that the second functional group is introduced by treatment of the solid phase carrier with a aminosilane coupling agent (Fig. 4, element # 42, column 6, lines 46-47).

Regarding claim 22, Chrisey et al teaches the substrate is the glass (Column 7, lines 24-33), which is a solid phase carrier of the instant claim.

Regarding claim 24, Chrisey et al teaches a method of immobilizing a probe to a solid phase carrier that include providing a DNA oligomers having thiol group, i.e., mercapto group (column 8, lines 41-67, Chrissey et al also refers to DNA oligomers as nucleic acid molecules, i.e., NAMs), that is plurality of probes and further teaches that DNA oligomers have a C3-C6 spacer molecules, i.e., linker molecule (column 9, lines 54-61) thus teaching a plurality of probes each having a linker containing –SH group. The –SH group of Chrissey et al is the first functional group of the said claim.

Chrissey et al further teaches an amino silane coating of the silica substrate (Fig. 4, element # 42, column 6, lines 45-47), thus teaching an immobilization substrate having an aminofunctional group. The amino functional group of Chrissey et al is the second functional group of the instant claim.

Chrissey et al also teaches that the substrate (column 6, lines 46-47) having an aminosilane coating at multiple locations thereon (Fig. 4, element # 42) binds electrostatically with negatively charged DNA oligomers (Fig. 4, DNA oligomer-element # 48; left and right bottom panels, column 6, lines 45-54) and further teaches that DNA

oligomer immobilized via electrostatic means on an organosilane monolayer is able to form duplexes selectively with its complementary partner, but will reject hybridization with a mismatched oligomer (Column 12 , lines 57-61), thus teaching imparting the probe to the immobilization substrate and by inherency, teaching binding of first functional group of the probe and the second functional group of the immobilization substrate to each other.

The mercapto and the amino group taught by Chrisey et al are also the acidic and basic functional group as defined in the instant specification (see instant specification, Paragraph 0036). Teachings of electrostatic binding, i.e., ionic interactions of DNA oligomer having the first functional group and immobilization substrate having second functional group of Chrisey et al thus encompass also first functional group and second functional group in the state of coupling without covalent binding.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (USPN 5,688,642 issued November 18, 1997) in view of McGovern et al (USPN 6,159,695 issued December 12, 2000).

Claim 18 is dependent on claim 14. Teachings of Chrisey et al regarding the claim 14 are described previously in this office action.

Regarding claim 18, Chrisey et al teaches immobilizing probe linker contains spacer molecules of C3-C6 (Column 9, lines 54-61). Chrisey et al do not teach the linker comprises a polyether chain. McGovern et al teaches attachment of tether linker to oligonucleotides (Fig. 4) with polyether linker of 2-50 unit (Column 22, lines 53 –58). McGovern et al also teaches tether linker supply the oligonucleotide with reactive functionality so that it can be chemically manipulated, and to allow the oligonucleotide to extend any specified distance away from the surface (Column 7, lines 18-22).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to use the oligonucleotide with tether linker with polyether chain as taught by McGovern et al as alternatives to the C3-C6 linker containing DNA oligomer of Chrisey et al. One would be motivated to do so to provide additional equivalent probes

and also with the expected benefit of providing additional reactive functionality so that probe can be chemically manipulated, thus allowing the oligonucleotide to extend any specified distance away from the surface as taught by McGovern et al (Column 7, lines 18-22) thus improving the DNA sensor capabilities of Chrisey et al.

Response to Remarks from the applicants

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

8. All rejections set forth under the § 112, Second Paragraph in the previous office action are withdrawn in view of applicant's amendment of the claims.

Claim Rejections Under 35 U.S.C. § 102(b)

9. Applicant argues that "the first functional group and the second functional group are in the state of coupling without covalent bonding" is not taught by Chrissey et al.

This argument is not found persuasive because as described previously in this office action, Chrissey et al teaches DNA oligomers modified with thiol groups (column 8, lines 41-67) and further teaches electrostatic binding of DNA oligomers with the immobilized aminosilane having amino terminal group (Fig. 4, see the electrostatic binding step and right and left bottom panels, column 6, lines 45-63) and further teaches that probe immobilization is very strong and withstands hybridization (Example 3, column 12, lines 27-61). Since as described previously in this office action, Chrissey et al teaches all of the recited steps of amended claim 14 and new claim 24 and therefore, applicant's argument is not found persuasive.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat., Ph. D.

Examiner

Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER